

Remarks/Arguments

Claims 1-7, 10, 12-19, 22, and 24 have been rejected as being anticipated under 35 U.S.C. § 102(b) or rendered obvious under 35 U.S.C. §103 by U.S. Patent 5,437,774 to *Laustsen* (“*Laustsen*”). Applicants again respectfully traverse the rejections on the basis that *Laustsen* fails to describe or suggest the claimed method.

I. Rejection under 35 U.S.C. § 102(b)

The Examiner states that *Laustsen* “discloses a range of values that fall within the claimed range and does not limit the reference to a preferred embodiment (see col. 7, lines 5-30).” Applicants do not disagree with the Examiner, but respectfully maintain that mere overlap of a claim with the disclosure of a reference does not necessarily support a *prima facie* case of anticipation. Rather, the Examiner must show that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” (MPEP § 2131; emphasis added)

A. Express Anticipation

The present claims state that “at least one of said at least one separation membrane has a molecular weight cutoff that is higher than but less than three times greater than the molecular weight cutoff of at least two of said at least two restriction membranes.” However, *Laustsen* does not expressly provide this limitation. Thus, in order to anticipate the claimed method, the Examiner must show that *Laustsen* “inherently” describes this limitation.

B. Inherent Anticipation

MPEP § 2112 (IV) states:

“The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however,

may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ”

In other words, in order for *Laustsen* to inherently anticipate the claimed method, the above-indicated limitation must “necessarily” be present in *Laustsen*. However, this is not the case. For example, *Laustsen* teaches that the “retention membranes” (i.e., restriction membranes) “preferably” have a molecular weight cutoff “below 10 kD”¹ and the separation membrane can have a molecular weight cutoff as high as “500 kD”² – i.e., a separation membrane can be selected having a molecular weight cutoff which is 50 times greater than the restriction membrane molecular weight cutoff -- rather than the “less than three times greater” provided by the claimed method. Thus, a separation membrane molecular weight cutoff which is “less than three times greater” than the molecular weight cutoff of the restriction membranes is not necessarily present in *Laustsen*, because some combinations of the separation and restriction membrane molecular weight cut-off values disclosed in *Laustsen* are outside of the claimed range. Accordingly, *Laustsen* fails to inherently describe this limitation.

II. Obviousness under 35 U.S.C. § 103(a)

MPEP § 2142 states:

“To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure.”

¹ *Laustsen* at col. 7, lines 26-27

² *Ibid.*, col. 7, line 17

In other words, in order to be support a *prima facie* case of obviousness, the Examiner must show that *Laustsen*:

- 1) teaches or suggests all of the claim limitations;
- 2) provides a suggestion or motivation for modifying the method(s) described therein to provide the claimed method; and
- 3) provides a reasonable expectation of success.

As indicated in Section I of this Response, *Laustsen* neither expressly or inherently discloses that “at least one of said at least one separation membrane has a molecular weight cutoff that is higher than but less than three times greater than the molecular weight cutoff of at least two of said at least two restriction membranes.” Accordingly, the Examiner must show that *Laustsen* suggests this limitation, i.e. by providing a suggestion or motivation to modify the methods disclosed therein to provide the claimed method.

However, *Laustsen* expressly states that the “[s]eparation membranes will have a molecular weight cutoff at least three times that of the retention membranes”.³ Applicants respectfully submit that this is an unequivocal teaching of *Laustsen* that the molecular weight cutoff of the separation membrane molecular “must” be selected to be at least three times greater than the molecular weight cutoff of the restriction membranes. That is, *Laustsen* expressly “teaches away” from the claimed method. Accordingly, *Laustsen* fails to suggest the claimed method.

III. Summary

Laustsen fails to support a *prima facie* case of anticipation because *Laustsen* neither expressly nor inherently teaches every element of the claimed method (*see* Section I, above).

Applicants also submit that *Laustsen* fails to support a *prima facie* case of obviousness because *Laustsen* expressly teaches away from the claimed invention.

Accordingly, Applicants respectfully request that the rejections be withdrawn.

³ *Ibid.*, col. 7, lines 27-29; emphasis added

The foregoing remarks are being made to place the application in a condition for allowance. Applicants respectfully request reconsideration of and the timely allowance of the pending claims. Should the Examiner find that an interview would be helpful to further prosecution of this application, he is invited to telephone the undersigned at his convenience.

Except for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-1283. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. 1.136(a)(3).

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COOLEY GODWARD KRONISH LLP
Customer No. 58249
1200 19th Street NW
5th Floor
Washington, DC 20036-2402
Tel: 202-842-7800

Respectfully submitted,
COOLEY GODWARD KRONISH LLP

By:

Thomas A. Blinka

Thomas A. Blinka
Reg. No. 44,541